IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	Confirmation No.: 2211
Scott E. Andersen *et al.*	Art Unit: 1634
Application Serial No.: 10/626,717	Examiner: Jehanne Sitton
Filed: July 25, 2003	Attorney Docket No.: 16517.301

Title: Nucleic Acid Molecules and Other Molecules Associated with Plants

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the Final Rejection of claims in the above-captioned patent application. A Notice of Appeal was filed on April 20, 2007. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellants identified the following judicial proceeding, which may have a bearing on the Board's decision in the present Appeal. On May 27, 2004, the Real Party in Interest in the above-captioned matter filed an appeal to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") from a decision by the Board in *In re Fisher.* (U.S. Patent Application

Serial No. 09/619,643; BPAI Appeal No. 2002-2046; Federal Circuit Case No. 04-1465). The Federal Circuit's decision in *In re Fisher* may have a bearing on the Board's decision with regard to at least one of the grounds of rejection in the present appeal. A copy of the Board's decision in Appeal No. 2002-2046, *Ex parte Fisher*, 72 U.S.P.Q.2d 1020 (Bd. Pat. App. Int. 2004), and a copy of *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) are attached hereto in the Related Proceedings Appendix.

The Real Party in Interest filed an Appeal Brief in U.S. Patent Application Serial No. 09/684,016; in U.S. Patent Application Serial No. 10/361,942; in U.S. Patent Application Serial No. 09/199,129; in U.S. Patent Application Serial No. 09/920,953; in U.S. Patent Application Serial No. 09/663,423; in U.S. Patent Application Serial No. 09/237,183; in U.S. Patent Application Serial No. 09/692,257; in U.S. Patent Application Serial No. 10/437,963; in U.S. Patent Application Serial No. 09/552,087; and in U.S. Patent Application Serial No. 09/531,113; which also may have a bearing on the present appeal.

3. Status of Claims

Claims 1 to 8 are pending. Claims 1 to 8 stand finally rejected under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph. Claims 1-4, 6, and 8 stand finally rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Appellants appeal the rejections of claims 1 to 8.

4. Status of Amendments

Appellants have filed an amendment on August 8, 2007 in response to the Final Office Action dated January 23, 2007 ("Final Action"). By this amendment, claims 1 and 3-6 have

been amended to coincide with Applicant's election with traverse of Group 3, directed to SEQ ID NO. 11 in the reply to the Office Action filed on May 22, 2006. The submitted amended claims can be found in Claims Appendix B. A listing of the pending claims prior to the filing of the above-stated amendment can be found in Claims Appendix A.

5. Summary of Claimed Subject Matter

Independent Claim 1. A substantially purified nucleic acid molecule comprising a nucleotide sequence having between 90% and 100% sequence identity with SEQ ID NO: 11 or the complement thereof.

Independent Claim 5: A substantially purified nucleic acid molecule consisting of a nucleotide sequence of SEQ ID NO: 11 or the complement thereof.

Independent Claim 6: A substantially purified nucleic acid molecule comprising a fragment from about 50 to about 100 nucleotide residues, wherein said fragment exhibits complete complementarity to SEQ ID NO: 11 or the complement thereof.

A copy of the claims on appeal is attached hereto in the Claims Appendix B.

6. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed in this Appeal are that pending claims 1 to 8 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, because the claimed invention allegedly lacks patentable utility, and that pending claims 1-4, 6, and 8 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement and written description requirement.

7. Argument

A. Summary of Appellants' Position

Appellants have provided a specific, substantial, and credible utility for a nucleic acid sequence that exhibits between 90% and 100% sequence identity to the nucleic acid sequence of SEQ ID NO: 11 and complement thereof. Appellants have provided a statistically significant correlation between the nucleic acid sequence of SEQ ID NO: 11 and a known protein. The correlation between SEQ ID NO: 11 and the known protein is specific and established by a well-known technique. In setting forth a reasonable correlation between the nucleic acid sequence of SEQ ID NO: 11 and the known protein, Appellants have demonstrated that the claimed invention has patentable utility and satisfies the written description requirement. In other words, Appellants have satisfied the requirements of 35 U.S.C. §§ 101 and 112, first paragraph.

B. The Claimed Nucleic Acids Have Utility under 35 U.S.C. § 101

The Examiner rejected claims 1 to 8 under 35 U.S.C. § 101, because the claimed invention allegedly "is not supported by either a specific or substantial asserted utility or a well established utility." Final Action at page 2.

In addition to the asserted utilities in the specification, Appellants have demonstrated the utility of SEQ ID NO: 11 by conducting a BLASTN analysis. The specification as filed discloses that a BLASTN analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. *Specification* page 5, line 19 to line 28. The results of a BLASTN analysis of SEQ ID NO: 11 show that SEQ ID NO: 11 has 99 percent identity to a storage-protein sequence obtained from *Triticum aestivum*. *See*, Appellants' Amendment under 37 C.F.R. § 1.111 filed on November 3, 2006 ("Amendment") at page 6.

Appellants respectfully submit that the results of the BLASTN analysis demonstrate that SEQ ID NO: 11 has utilities specific to it and not generally applicable to any nucleic acid.

In *In re Fisher*, the Federal Circuit reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (citing *Brenner v. Manson*, 383 U.S. at 534-35, 1966) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*." *Id.* (emphasis in original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

The Examiner states that "it is not clear or apparent what reasonable correlation is determined from 99% identity over only a portion of SEQ ID NO: 11 (66%) with a (known protein-encoding) sequence..." Final Action at page 9. Appellants respectfully submit that the Examiner has not disclosed the parameters used to determine that the storage-protein encoding sequence is 99% identical to only a portion (66%) of SEQ ID NO: 11. Even if the Examiner's determination is correct, Appellants respectfully submit that by showing that the claimed SEQ ID NO: 11 is reasonably correlated with a known protein, the utility of SEQ ID NO: 11 is specific, substantial, and credible. The utility of SEQ ID NO: 11 is *specific* because it is specific to SEQ ID NO: 11 and not generally to any nucleic acid sequence. In other words, 66 percent of SEQ ID NO: 11, and not just any general nucleic acid sequence, shares 99 percent identity to a storage-protein sequence obtained from *Triticum aestivum*, according to the Examiner. This utility is *substantial* and *credible* because the nucleic acid molecules of the present invention can be used to isolate genes, map genes, and determine gene function associated with protein storage. Storage proteins (in plants) are important for human nutrition. Furthermore, there exists an interest in the production of mutants with an increased protein content or an increased amount of essential amino acids. *See, e.g.*, http://www.biologie.uni-hamburg.de/b-online/e17/17i.htm (accessed on June 4, 2007) (providing an introduction to storage proteins in plants). These utilities are substantial and credible, not vague or impractical.

The Office must accept a stated utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the applicant's assertion. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing

nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion." Federal Register 66(4):1096, Utility Guidelines (2001). Furthermore, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565 (Fed. Cir. 1996). "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, Rev. 5 at page 2100-34. The BLASTN analysis provides such a reasonable correlation through sequence identity. The 99 percent identity of storage-protein sequence obtained from *Triticum aestivum* to 66 percent of SEQ ID NO: 11 is a reasonable correlation.

The Office "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25 (C.C.P.A. 1975) (emphasis in original); M.P.E.P. § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided…"). Here, the Examiner has not met this burden.

The Examiner has provided no support for the assertion that the utilities of SEQ ID NO: 11 are not specific, substantial, and credible. Rather, the Examiner's position is that "the utility is not specific because it is a property of all wheat plant nucleic acids..." Final Action at page 4. The Examiner's analysis is not in accordance with the ruling of *In re Fisher*.

While it is true that any nucleic acid sequence can be used for a BLASTN search to obtain sequences that share homology with it, a random or general nucleic acid sequence does not share 99 percent identity to a storage-protein sequence obtained from *Triticum aestivum*, which SEQ ID NO: 11 does. Amendment at page 6. Whether or not further research is required to find any specific or substantial utility for the sequence obtained from the BLASTN search (*i.e.*, the sequence obtained by Kawaura *et al.*) is not legally relevant to the determination of whether SEQ ID NO: 11 has specific, substantial, or credible utility. Moreover, Appellants respectfully submit that the Examiner has provided no proof that the Kawaura *et al.* sequence is "only an EST sequence" or that it has an "unknown function for the protein it encodes, if any." Regardless, Appellants respectfully submit that, no matter what the Kawaura *et al.* sequence is, or is not, *knowing* that it shares such a strong identity with SEQ ID NO: 11 would lead one of ordinary skill in the art to recognize that the claimed invention can be used in a manner that provides some immediate benefit to the public, *In re Fisher*, 421 F.3d at 1371, for example to develop plants with enhanced protein storage ability.

In conclusion, Appellants respectfully submit that SEQ ID NO: 11 has specific, substantial, or credible utility because it has a reasonable correlation with a storage-protein sequence obtained from *Triticum aestivum*, and can be used in a manner that provides some immediate benefit to the public In other words, the claimed invention meets the utility test set

forth in *In re Fisher*. Therefore, Appellants respectfully request that the Board reverse the rejection of claims 1 to 8 under 35 U.S.C. § 101.

C. The Claimed Nucleic Acids Satisfy the Enablement Requirement of 35 U.S.C. § 112

The Examiner rejected claims 1-4, 6, and 8 under 35 U.S.C. § 112, first paragraph, because, allegedly, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility, "one skilled in the art clearly would not know how to use the claimed invention". Final Action at page 6.

Appellants submit that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. In other words, Appellants respectfully submit that the claimed invention has specific, substantial, and credible utility and request that the Board reverse the rejection of claims 1 to 8 under the enablement requirement of 35 U.S.C. § 112, first paragraph.

D. The Claimed Nucleic Acids Satisfy the Written Description Requirement of 35 U.S.C. § 112

The Examiner rejected claims 1-4, 6 and 8 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter not described in the specification, *i.e.*, failing to comply with the written description requirement. Final Action at page 9. The Examiner admits that nucleic acids consisting of SEQ ID NO: 11 satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. *Id.* at page 10. The Examiner asserts, however, that "SEQ ID NO: 11 is an EST, and is less than a full length open reading frame," and accordingly Applicants have allegedly not adequately disclosed the claimed genera of nucleic acid molecules. *Id.* As such,

the Examiner appears to require that each nucleic acid molecule within the claimed genera must be described by its complete structure. *Id.* This requirement is unfounded.

In particular, Applicants have disclosed common structural features of the genus of claimed nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 11. For example, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 11.[1] Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequence of SEQ ID NO: 11 or share a claimed identity with SEQ ID NO: 11, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1-4, 6, and 8 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

The Examiner's position, however, is that "the specification does not disclose what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature." *Id* at page 15. This analysis misses the point of the written description requirement. The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject

[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule contains a nucleic acid sequence that has 95% identity with SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules having between 95% and 100% identity with SEQ ID NO: 11. *See* claim 4.

matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). In accordance with this purpose, Appellants need not "describe," in the sense of 35 U.S.C. § 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). Thus, in order for Appellants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton*, 76 F.3d at 1175 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met).

An adequate written description of a genus of nucleic acids, such as those recited in claims 1-4, 6, and 8, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.* Further, Appellants need not describe every possible

sequence that may be included in the claimed genus of nucleic acid molecules. Indeed, recently, the Federal Circuit stated that "[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Appellants have satisfied this requirement.

The specification provides the chemical formula of SEQ ID NO: 11 and this chemical structure clearly distinguishes molecules in the claimed genus from molecules not in the claimed genus. Nucleic acid molecules falling within the scope of claims 1-4, 6, and 8 are readily identifiable and one of ordinary skill in the art can readily identify whether a particular sequence meets the claimed characteristics or not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

The Examiner states that the"genus of polynucleotides comprised by the claims is a large variable genus, which can potentially encode proteins of diverse functions...it is not clear which positions with SEQ ID NO:11 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 11...therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 11." Final Action at page 12. Applicants respectfully disagree because one of ordinary skill in the art would be reasonably able to predict which changes would result in loss of function. As the M.P.E.P. clearly states that "(i)f one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art." M.P.E.P. § 2164.03. For example, the specification as filed provides ample knowledge of "conservative" changes.

The specification makes clear (and as one of ordinary skill in the art is aware), conservative substitutions generally retain functionality while non-conservative substitutions generally do not. *See, for example,* Specification at pages 19 and 20. In other words, one of ordinary skill in the art can readily anticipate the effects of substitutions or deletions on the nucleic acid molecules of the claimed invention.

The Examiner states that the "claims 1-4, 6, and 8, due to the language 'comprising' encompass a large genus of sequences which are larger than SEQ ID NO: 11." Final Action at page 10. The Examiner further states that "the specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 11, which is insufficient to put one of skill in the art in possession of all attributes and features of all species within the genus." Final Action at page 12. However, the Examiner has offered no evidence to demonstrate why one of ordinary skill in the art would reasonably doubt that Appellants have adequately described the claimed invention in the present disclosure. Whether or not the genus is large or variable, it shares a common feature, *i.e.*, the sequence of SEQ ID NO: 11, and one of ordinary skill in the art would recognize that Appellants were in possession of the genus of nucleic acid molecules comprising a nucleic acid sequence having between 90% and 100% identity to the nucleic acid molecule of SEQ ID NO: 11.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that Appellants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). An Applicant shows possession of the claimed invention by describing the claimed invention with all of its

limitations. *Lockwood*, 107 F.3d at 1572; M.P.E.P. § 2163.02. In light of the disclosure of the specification one of ordinary skill in the art at the time the application was filed would have readily recognized that Appellants were in possession of the invention as claimed.

By describing the common structural feature of the claimed nucleic acid molecules, i.e., SEQ ID NO: 11, Appellants respectfully submit that they have satisfied, at least, the Eli Lilly test for written description. Therefore, Appellants respectfully request that the Board reverse the rejection of claims 1-4, 6, and 8 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: **August 8, 2007**

Holly L. Prutz (Reg. Attorney No. 47,755)
David R. Marsh (Reg. Attorney No. 41,408)
Arnold & Porter LLP
555 Twelfth Street, N.W.
Attn: IP Docketing
Washington, DC 20004
Tel: 202-942-5000
Fax: 202-942-5999

CORRESPONDENCE ADDRESS:
Monsanto Company
800 N. Lindbergh Blvd.
Attn: Gail P. Wuellner, IP Paralegal
IP Paralegal (E2NA)
St. Louis, Missouri 63167

CLAIMS APPENDIX A

Claim 1. A substantially purified nucleic acid molecule comprising a nucleotide sequence having between 90% and 100% sequence identity with a sequence selected from the group consisting of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 and the complements thereof.

Claim 2. The substantially purified nucleic acid molecule of claim 1, wherein said nucleic acid molecule encodes a wheat protein or fragment of a wheat protein.

Claim 3. The substantially purified nucleic acid molecule of claim 1, wherein said nucleotide sequence is selected from the group consisting of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17 and 18.

Claim 4. The substantially purified nucleic acid molecule of claim 1, wherein said nucleotide sequence has between 95% and 100% sequence identity with a sequence selected from the group consisting of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 and the complements thereof.

Claim 5. A substantially purified nucleic acid molecule consisting of a nucleotide sequence selected from the group consisting of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 and the complements thereof.

Claim 6. A substantially purified nucleic acid molecule comprising a fragment from about 50 to about 100 nucleotide residues, wherein said fragment exhibits complete complementarity to a sequence selected from the group consisting of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 and the complements thereof.

Claim 7. The substantially purified nucleic acid molecule of claim 6, where said nucleic acid molecule consists of said fragment.

Claim 8. The substantially purified nucleic acid molecule of claim 6, wherein said substantially purified nucleic acid molecule further comprises a region having a single nucleotide polymorphism.

CLAIMS APPENDIX B

Claim 1. A substantially purified nucleic acid molecule comprising a nucleotide sequence having between 90% and 100% sequence identity with SEQ ID NO: 11 or the complement thereof.

Claim 2. The substantially purified nucleic acid molecule of claim 1, wherein said nucleic acid molecule encodes a wheat protein or fragment of a wheat protein.

Claim 3. The substantially purified nucleic acid molecule of claim 1, wherein said nucleotide sequence is SEQ ID NO: 11.

Claim 4. The substantially purified nucleic acid molecule of claim 1, wherein said nucleotide sequence has between 95% and 100% sequence identity with SEQ ID NO: 11 or the complement thereof.

Claim 5. A substantially purified nucleic acid molecule consisting of a nucleotide sequence of SEQ ID NO: 11 or the complement thereof.

Claim 6. A substantially purified nucleic acid molecule comprising a fragment from about 50 to about 100 nucleotide residues, wherein said fragment exhibits complete complementarity to SEQ ID NO: 11 or the complement thereof.

Claim 7. The substantially purified nucleic acid molecule of claim 6, where said nucleic acid molecule consists of said fragment.

Claim 8. The substantially purified nucleic acid molecule of claim 6, wherein said substantially purified nucleic acid molecule further comprises a region having a single nucleotide polymorphism.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

Copies of the following are attached:

1. *Ex parte Fisher*, 72 U.S.P.Q.2d 1020 (Bd. Pat. App. Int. 2004);
2. *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005);
3. Appeal Brief filed in U.S. Patent Application Serial No. 09/684,016;
4. Appeal Brief filed in U.S. Patent Application Serial No. 10/361,942;
5. Appeal Brief filed in U.S. Patent Application Serial No. 09/199,129;
6. Appeal Brief filed in U.S. Patent Application Serial No. 09/920,953;
7. Appeal Brief filed in U.S. Patent Application Serial No. 09/663,423;
8. Appeal Brief filed in U.S. Patent Application Serial No. 09/237,183;
9. Appeal Brief filed in U.S. Patent Application Serial No. 09/692,257;
10. Appeal Brief filed in U.S. Patent Application Serial No. 10/437,963;
11. Appeal Brief filed in U.S. Patent Application Serial No. 09/552,087; and
12. Appeal Brief filed in U.S. Patent Application Serial No. 09/531,113.